UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,571	03/03/2004	Neil T Dear	ABB10010P0630US	9704

32116 7590 08/08/2006

WOOD, PHILLIPS, KATZ, CLARK & MORTIMER
500 W. MADISON STREET
SUITE 3800
CHICAGO, IL 60661

EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,571	DEAR ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) *6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0402*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Invention I, Claims 1-5, in their response of June 5, 2006 is acknowledged. Applicants' traversal is based on the arguments that (1) Groups I and II are linked by a single inventive concept, the polypeptide of SEQ ID NO: 2 for the regulation of fertility in men and (2) searching both inventions would not be a burden. These arguments are not found to be persuasive for the following reasons. First, none of Claims 1-5 recite any functional limitation of regulating fertility in men and the specification fails to disclose such a function for the protein of SEQ ID NO: 2 or the encoding polynucleotide. Second, the method of Group II does not use the polynucleotide or polypeptide of Group I and does not share a special technical feature of mode of operation, functions, or effects with the method of Group I. Third, searching the method of Group II, treatment of fertility disorders in men (class 514, subclass 1), would not overlap the search for Group I, identifying inhibitors of the polypeptide of SEQ ID NO: 2 (class 435, subclass 226) and searching both would be a burden on the Office. For these reasons and those presented in the prior Restriction/Election, the restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-6 are pending. Claim 6 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1-5 are hereby examined.

Priority

The priority date of the instant invention is taken to be June 18, 1999, the filing date of Germany 199 28 021.5, which discloses SEQ ID NO: 1 and 2.

Drawings

Figure 1 is objected to for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO:). The sequence rules embrace all nucleotide sequences with ten or more bases and all amino acid sequences with four or more amino acids. Said sequences must be disclosed in a sequence listing and identified by a specific SEQ ID NO: (MPEP 2421.02). 37 CFR 1.821(d) requires the use of the assigned sequence identifier number in all instances where the description or claims of a patent application discuss sequences, regardless of whether a given sequence is also embedded in the text of the description or claims of an application. Applicant is required to check the drawings and specification completely and to make corrections to identify all of the sequences disclosed therein by sequence identifier numbers.

Title

The title is objected to for use of the word "Novel". All patents are presumed to be novel.

Specification-Objections

The specification is objected to for improper formatting. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without

underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The specification is also objected to for containing hyperlinks, for example on page 6. USPTO policy does not permit the USPTO, i.e, via an issued patent, to link to any commercial sites, since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. Hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not to be included in a patent application. (MPEP 608.01) The specification should be carefully checked and all URLs removed.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Utility

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The specification fails to teach a specific and substantial function for the protein set forth by SEQ ID NO: 2, or the encoding polynucleotide. Based on the title and the specification (pg 1, pargs 2 and 6), the asserted utility for said protein is as a calpain-family protease. Said assertion is not specific and substantial for the following reasons. As acknowledged by Applicants (pg 1, parg 4), the prior art teaches that the calpain-family of protease is diverse and, in many cases, the cellular function of calpain-family proteins is not known (Goll et al, 2003; pg 771, parg 4). The specification fails to assert a specific function, as calpain-family protease, for the protein of SEQ ID NO: 2. Mere assertion that a protein is a member of the calpain-family of proteases is not an assertion of a specification and substantial utility.

The specification fails provide evidence for a specific function for the protein of SEQ ID NO: 2. No substrates for said protein are identified. Moreover, the prior art teaches that, although calpain-family proteases cleave a large number of proteins in vitro, evidence that said proteins are cleaved in vivo is lacking (Goll et al, pgs 773, parg 5 – 776, parg 1). The specification also fails to teach any biochemical or cellular process that the protein of SEQ ID NO: 2 mediates or modulates or any disease caused by or treatable by said protein or the

encoding polynucleotide. Without such evidence the skilled artisan would clearly not know how to use the recited invention.

It is acknowledged that the specification asserts that the polypeptide of SEQ ID NO: 2 is most homologous to the μ/m calpain of chicken (pg 1, parg 7). However, said assertion of structural similarity is not an assertion of function. Even if said assertion of structural homology were an assertion of function, which it is not, neither the specification nor the prior art provide evidence as to a specific and substantial function for the protein of SEQ ID NO: 2 as the human homolog of the μ/m calpain of chicken. The specification fails to provide evidence that the substrates or cellular function of the protein of SEQ ID NO: 2 is the same as the substrates or function of the μ/m calpain of chicken. Moreover, at the time of filing, neither the substrates nor function of the μ/m calpain of chicken were known. The μ/m calpain of chicken was cloned in 1998, but the substrates and function were not disclosed (Ohno et al, 1998). The human homolog, calpain-11 as set forth by SEQ ID NO: 2 herein, was disclosed in 1999, but again the substrates and function were not disclosed (Dear et al, 1999; IDS). In fact, as recently as 2006, Ben-Aharon et al reported that the substrates and function of calpain-11 have yet to be determined (Ben-Aharon et al, 2006; pg 772, parg 4). Thus, even if Applicants' assertion of structural homology were an assertion of function, the function of the protein of SEQ ID NO: 2 cannot be deduced from said homology because the function of μ/m calpain of chicken, the homolog of mammalian calpain-11, is not known. Therefore, no evidence for a patentable utility for the protein of SEQ ID NO: 2 or the encoding polynucleotide is provided by the specification or the prior art.

For these reasons, Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention lacks a substantial and specific utility.

Claims 1-5 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claim 1, it is unclear whether the phrase "having the amino acid sequence SEQ ID NO: 2" means "consisting of the amino acid sequence SEQ ID NO: 2" or "comprising the amino acid sequence SEQ ID NO: 2". For purpose of examination, it is assumed that said phrase means "consisting of the amino acid sequence SEQ ID NO: 2".

Claims 2, 4, and 5 are indefinite due to improper antecedent usage as follows.

For Claims 2 and 5, "a polypeptide as claimed in Claim 1" should be corrected to "the polypeptide as claimed in Claim 1".

For Claim 4, "a polypeptide as claimed in Claim 2" should be corrected to "the polypeptide as claimed in Claim 2".

For Claim 4, "this polypeptide" should be corrected to "the polypeptide".

Written Description

Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 4 and 5 are directed to a method for identifying modulators of the activity of the polypeptide set forth by SEQ ID NO: 2. The specification teaches no such methods. Given this lack of description of representative methods encompassed by the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
Art Unit 1656